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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,496

Applicant(s)

MONTIJN ET AL.

Examiner

Amanda P. Wood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 2, and 4-9 are rendered vague and indefinite because they fail to adequately define a complete method with respect to the recited preamble language - e.g., claims 1 and 2 vaguely recite a one-step method which would not appear to provide the necessary method steps for accomplishing the goal set forth in each of the preamble recitations. Accordingly, these claims, as drafted, are deemed incomplete and, thus, indefinite.

Claims 10 and 11 provide for the use of, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Duncan et al (Letters in Applied Microbiology 2000).

A method for determining an environmental condition by measuring a biochemical composition of one or more microorganisms exposed to said environmental condition is claimed.

Duncan et al teach a method of determining whether toxic compounds have perturbed a wastewater treatment process (i.e., an environmental condition) by measuring the amount of a stress protein (i.e., a biochemical composition) expressed by the diverse population of microorganisms in the wastewater treatment process. Furthermore, Duncan et al teach that changes in the environmental condition of the treatment process can be monitored by measuring the changes in the amount of stress protein expressed by these microorganisms, and that protein induction patterns, or protein fingerprints, in these activated sludge cultures can be determined and used in monitoring the treatment process (see, for example, Abstract and Introduction, pgs 28-29). Duncan et al teach that a diverse population of microorganisms exist in these activated sludge cultures, but in particular, *E. coli*, *Rhodobacter sphaeroides*, *Nitrosomonas europaea*, *Sphingomonas capsulata* and *Pseudomonas putida* were used by Duncan et al. In addition, Duncan et al measured the amount of the general shock protein GroEL that was induced in the cells of these bacteria in response to the contamination of the wastewater treatment process (i.e., a bioconversion process in an aqueous environment) under different environmental conditions. Duncan et al further teach that relative levels of stress proteins in conjunction with their induction patterns

will lead to the development of a useful monitoring technology based upon microbial stress response.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan et al in view of Larossa et al (US 6,607,885).

Duncan et al is relied upon for the reasons set forth above.

Duncan et al do not specifically teach a method wherein the biochemical composition is the transcriptome (i.e., measurement of mRNA levels present in a cell), nor a method wherein the biochemical composition is determined using microarrays.

Larossa et al beneficially teach a method wherein the effect of environmental changes is determined by measuring gene expression levels (i.e., the transcriptome) in bacteria. Larossa et al specifically teach that *E. coli* experiments to define stress-related responses in the past have used mRNA measurements to determine an individual gene's expression profile (see, for example col. 1, lines 30-60 and col. 2, lines 20-65).

In addition, Larossa et al beneficially teach a method wherein a bacterial species is subjected to a gene expression altering condition (i.e., an environmental condition) and a microarray of the bacterial RNA is generated so as to identify the gene expression level and changes in the bacteria. Furthermore, Larossa et al beneficially teach that it is possible to monitor the effect of environmental changes on gene expression by comparing expression levels of genes from bacteria that have not been exposed to stress to those of bacteria that have been exposed to stress.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Duncan et al based upon the beneficial teachings provided by the secondary reference with respect to the art-recognized method of using microorganisms to monitor the environmental condition or changes in the condition as discussed above. Furthermore, the cited references particularly point out that the level of a protein such as a stress protein (i.e., a biochemical composition) can be measured in bacteria that have been exposed to an environmental condition, such as contamination by toxic compounds, and that it would be beneficial to develop a monitoring technology using relative levels of stress proteins in conjunction with their induction patterns. In addition, the cited references particularly point out that microarrays can be used to determine the amount of RNA or protein a microorganism, such as bacteria, expresses upon exposure to a stressor, such as a change in environmental condition, and therefore, it would have been obvious and beneficial for the skilled artisan to use the methods taught by Duncan et al so as to determine an environmental condition by measuring a biochemical composition of one

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or more microorganisms. The result-effective adjustment of particular conventional working conditions (e.g., using a particular microorganism, measuring a particular biochemical composition, and/or using a particular method to determine the biochemical composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

APW
Examiner
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APW



CHRISTOPHER R. TATE
PRIMARY EXAMINER